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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex Parte SHINICHIRO MORITA, TOSHIHARU SHIN'OKA,
and YASUHARU IMAI

Appeal 2008-005884
Application 10/070,938
Technology Center 1600

Oral Hearing Held: May 21, 2009

Before DEMETRA J. MILLS, LORA M. GREEN, and JEFFREY N. FREDMAN. *Administrative Patent Judges.*

APPEARANCES.

ON BEHALF OF THE APPELLANT:

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PROCEEDINGS

MS. BEAN: Calendar No. 64. Mr. Altman.

JUDGE MILLS: Good afternoon, Mr. Altman.

1 MR. ALTMAN: Good afternoon to all of you.

2 JUDGE MILLS: We're familiar with your case, and you have 20
3 minutes, and you may begin when you're ready.

4 MR. ALTMAN: Okay, thank you very much. So I want to focus on
5 just a couple of the issues that we're presenting in our Appeal Brief and
6 focus the direction of the hearing on those issues.

7 JUDGE MILLS: That's fine.

8 MR. ALTMAN: And in particular, there are two rejections of the sole
9 independent claim which are -- which is claim 7, and the two rejections, of
10 course, is there's one combination of three references, and then there is also
11 a rejection over this Naughton reference.

12 And the issue -- the first issue that I wanted to focus on is the issue
13 that our inventors discovered the source of a problem, and in the
14 specification there's a short discussion of the prior art and how there is
15 extensive prior art in the area of, of vascular or other types of tissue grafts.
16 And one problem that was identified in the, in the vascular tissue grafts for
17 cardiovascular purposes is that when you use a non-biodegradable implant
18 that the non-biodegradable implant can lead to problems, that stenosis can
19 occur around the implant. And so these biodegradable implants were
20 developed that are the subject of the claims.

21 One risk with biodegradable implants, though, is that every once in a
22 while they can lead to sudden failure, and the sudden failure can result in
23 death. It's a very bad problem. So what this invention resulted from is that
24 our inventors identified what the source of that risk of sudden cardiac failure
25 when using a biodegradable implant was, and what they discovered is the

1 biodegradable material, it stays in for quite a while in the body, but if it
2 degrades too quickly, then the autogenous material which is expected to
3 develop around the implant has not yet finished developing. And so if it
4 breaks down too quickly, then the, the risk of sudden cardiac failure results,
5 so --

6 JUDGE GREEN: But isn't some of that in Morita when they talk
7 about the sponge with the poly-L-lactic acid? They say it is possible to
8 maintain the structural pores of the sponge over a long period of time?

9 MR. ALTMAN: Yes. Well, Morita -- what Morita addresses is, is
10 something that's really quite different, because Morita is addressing the
11 situation with wounds, defects and orthopedic surgery, and these are big,
12 these are big holes that need to be filled, and that's quite different than in a
13 cardiac situation which is the, which is the, the claimed method which,
14 which involves necessarily implanting in the heart. And so you would
15 expect that in, in the Morita prior art that there would be a need for
16 reinforcement there, because you're trying to fill a big hole that resulted
17 from a wound. So it's really not the same thing as what's being addressed in
18 the present application.

19 JUDGE GREEN: But didn't they talk about a collagen sponge, right,
20 that is used for -- that provides something for tissues -- I mean for cells to be
21 able to colonize on?

22 MR. ALTMAN: Yes, I agree with that.

23 JUDGE GREEN: Okay.

24 JUDGE FREDMAN: And your claim isn't really heart only. It's
25 blood vessels, so it's really a vascular -- it could, it could read on making

1 vessels with vascular -- muscle cells, right? I mean your claim, claim 8 says
2 where the cardiovascular tissue regenerated to the blood vessel.

3 MR. ALTMAN: Right, I see. Yes, of course.

4 JUDGE FREDMAN: So claim 7 presumably encompasses the same
5 thing.

6 MR. ALTMAN: Right. I did, I did over generalize a bit, I agree. But
7 what we're talking about is something completely different than filling a big
8 hole during orthopedic surgery and --

9 JUDGE FREDMAN: So you don't think the --

10 MR. ALTMAN: -- or a wound --

11 JUDGE FREDMAN: -- bigger hole is going to get colonized by
12 vascular -- muscle cells and cause arteries to form inside of it and veins,
13 especially the other --

14 MR. ALTMAN: I'm sorry. I just didn't --

15 JUDGE FREDMAN: I'm just curious. I mean when you say if you
16 have a big hole, typically when you repair that is one of the things that will
17 colonize in this area is -- yeah, I mean you're going to get angiogenesis,
18 right?

19 MR. ALTMAN: It's possible. I could imagine that that might
20 happen.

21 JUDGE FREDMAN: But I would think it would typically happen, or
22 you're knocking out blood supply to that part of the body which would be
23 kind of a problem.

24

25

1 MR. ALTMAN: Let me think about that. That does make sense. I
2 mean Morita was addressing, was addressing this problem. He said you
3 need to fill in a big space that's missing after surgery or after a wound.

4 JUDGE FREDMAN: Right.

5 MR. ALTMAN: And yes, of course you're going to need to have,
6 you're going to need to have all the tissue regenerate in there. But, but
7 otherwise, you know, you've seen probably people with wounds in their arm
8 where they have gotten a big shark bite or something, and they need to fill
9 that.

10 JUDGE FREDMAN: Right.

11 JUDGE GREEN: But Morita doesn't talk about big spaces. He just
12 talks about surgery and, and wounds.

13 MR. ALTMAN: No, I understand.

14 JUDGE GREEN: I mean, it could be laparoscopic that they're filling
15 and the wound is --

16 JUDGE FREDMAN: Small.

17 JUDGE GREEN: -- small. I mean, there's nothing in here --

18 MR. ALTMAN: It's conceivable but that's not -- Morita -- this was --
19 it's -- there's not very much to Morita --

20 JUDGE GREEN: I admit that it's not going specifically towards
21 blood vessels, but it talks about using a collage sponge that has been
22 reinforced with this, this fiber for use in vivo to repair something in the
23 body.

24

25

1 MR. ALTMAN: Yes, I do agree with that, except that there is no
2 disclosure in Morita -- there's not much disclosure in that Morita paper at all.
3 There --

4 JUDGE GREEN: No, I understand that, but I'm just saying but it
5 does -- that's what it deals with is using this collagen sponge that's been
6 reinforced with these polylactic acid fibers for use for repair in the body,
7 though they do not specifically talk about cardiovascular tissue.

8 MR. ALTMAN: That's right. So there's no risk of sudden cardiac
9 failure in Morita, because that's not what, that's not what's occurring there.
10 He's filling, filling in a wound.

11 JUDGE GREEN: I understand.

12 MR. ALTMAN: And so that's why what I, what I was trying to
13 address in, in the argument was that, was that it wasn't really known what
14 the source of this risk of sudden failure of the graft was when they switched
15 to biodegradable materials and, and it was our inventor's discovery that what
16 was happening was that these biodegradable materials, although they don't
17 degrade super quickly, they might degrade too quickly in the absence of the,
18 the recited biodegradable reinforcements and that if they degrade too quickly
19 that that can lead to the sudden failure that results in, in death and other
20 problems as well.

21 And really none of the prior art recognizes this problem at all. We
22 already talked about Morita and its, its use as a filler.

23 JUDGE GREEN: But the art doesn't have to be addressing the same
24 problem, right?

25

1 MR. ALTMAN: No, and that's why I'm, I'm not talking about the, the
2 reason to combine the references. I'm talking about something else entirely
3 which is that the art did not identify the problem that was discovered by our
4 inventors.

5 And what the problem of Vacanti, Vacanti has this bioabsorbable
6 material, and there's a disclosure in Vacanti about some struts that the
7 Examiner was reading on, on our reinforcing material. And the struts
8 though were, were disclosed only in connection with things that had a
9 particular shape that needed to be maintained. So at the bottom of page 3 on
10 Vacanti, he talks about that the struts can be used to thereby yield a desired
11 shape, such as a heart valve or a tube. So the idea behind the strut there is
12 not to reinforce the material such that it would prevent failure but to keep the
13 thing in the shape that was desired. So although he had a reinforcement,
14 they didn't recognize the problem that our Inventors addressed.

15 And similarly, Vyakarnam talks about putting in a reinforcement but
16 only in the portion -- Vyakarnam is about repairing bones, and so he's
17 putting in reinforcement only in that portion of the matrix which contacts the
18 bone. He says that while that particular portion may require some
19 reinforcement, and so if you want to you can put reinforcement in that
20 portion. So again, he is not talking about this thing breaking down too
21 quickly. He's saying that when you, when you need to attach to the bone,
22 that attachment point may require some reinforcement.

23 And the, the various references that were cited --

24 JUDGE FREDMAN: So the -- but the question I would ask I guess is
25 the Examiner doesn't need to have the same reason for combining, right. So

1 he can argue that it's obvious even if he doesn't have your same advantage
2 and --

3 MR. ALTMAN: I agree with that.

4 JUDGE FREDMAN: -- and so how are you arguing that if I'm not --
5 are you arguing that you have a secondary consideration of some sort?

6 MR. ALTMAN: Well, what I'm arguing is that our inventors
7 discovered that there was, there was this problem that was recognized in the
8 art, and the problem was that there was a risk of sudden failure.

9 JUDGE FREDMAN: Absolutely. But -- so what legal theory are you
10 proposing that the 103 is not obvious?

11 MR. ALTMAN: Yeah, so the legal theory is that the discovery of the
12 source of a problem can be a non-obvious invention even if the solution
13 itself is obvious once you know the source of the problem.

14 JUDGE GREEN: But do you have any post-KSR case law that
15 supports that?

16 MR. ALTMAN: Well, I did think about that. I know that in the
17 appeal brief we had some old CCPA cases that supported this proposition.
18 But KSR really does nothing that says that that would change that.

19 JUDGE GREEN: But, but we do have -- also have the -- but we have
20 in KSR obvious to try if you have a number of defined limited solutions.
21 Here we have a collage matrix, one with lactic acid, one without lactic acid
22 would have been obvious to try to use it. The other thing that we have is we
23 have -- this has, has increased strength. So why wouldn't you want to use it
24 in, in vivo even without the knowledge of knowing that there may be a
25 catastrophic failure, because of course you're going to want something to last

1 long enough to, to be -- so that you know it can -- the body can repair itself.

2 I mean that's kind of --

3 JUDGE FREDMAN: And arguably in this context, I mean people of
4 I think ordinary skill in the art here, which would be people who are working
5 in, you know, vascular reconstruction, would recognize that, that you want
6 things that are reasonably strong, and the restenosis is, is a well-known
7 problem. It's a very old problem and, you know, if anyone could look at an
8 angioplasty, they were aware of these sorts of problems.

9 JUDGE GREEN: And then they understand the mechanical problems

10 --

11 MR. ALTMAN: Yeah, well, let me -- can I, can I --
12 because now I'm getting confused because we're now addressing -- we're,
13 we're adding all these different things. Can I address your comment first and
14 then yours?

15 JUDGE GREEN: Yeah.

16 JUDGE FREDMAN: Absolutely.

17 MR. ALTMAN: Thank you very much. I'm coming from bio and,
18 and my brain is not quite ready to, to take on so many things at the same
19 time.

20 So the one issue you raised first is the obvious to try issue and, and so
21 yes, I agree. It's sometimes obvious to try in the, in the absence of a, of a
22 likelihood of success can lead to a *prima facie* case of obviousness, and I
23 agree with that concept. I mean certainly that's what KSR says. But, but
24 this argument is a little bit different, because this argument is not that it's
25

1 obvious to try. This, this argument is that the problem really wasn't
2 identified.

3 JUDGE GREEN: I understand that, but we don't have to have a
4 recognition of the problem to make the invention obvious, and that's what
5 I'm trying -- I'm trying to get you away from the recognition of the problem.
6 Whether or not this problem was recognized, would the ordinary artisan with
7 these references in front of him been motivated to make the combination
8 regardless of whether this problem was recognized or not? And that's where
9 the obvious to try and some of these other issue in KSR come about, because
10 you had this teaching in Morita of the exact same scaffold that you're using,
11 and it's saying that it has good properties, good -- strength, it lasts for a
12 while and that it provides a good place for cells to come in and colonize.

13 MR. ALTMAN: Okay, I see what your point is, and in Morita it's as I
14 mentioned earlier --

15 JUDGE GREEN: But, but you can take it out --

16 MR. ALTMAN: -- that's something completely different.

17 JUDGE GREEN: But KSR also says if you can -- if something has
18 been used in one place, and the ordinary artisan would understand you could
19 use it someplace else, what's not obvious unless it would have been beyond
20 the level of skill of the ordinary artisan. What would have been beyond the,
21 the level of skill of the ordinary artisan?

22 MR. ALTMAN: Because what was happening in these devices, the
23 difficulty is that they broke down. I mean, that's what our
24 inventors discovered.

25 JUDGE GREEN: But that's the problem again.

1 MR. ALTMAN: They broke down too quickly.

2 JUDGE GREEN: We're coming back to the problem. Why --

3 MR. ALTMAN: And so it's only obvious to try once you can identify
4 that there is a problem.

5 JUDGE GREEN: But wouldn't you say that the ordinary artisan in
6 vascular surgery would understand that there are certain stresses on
7 especially arteries and the heart and the heart valve and everything else, that
8 there are certain mechanical things that -- mechanical that they, they would
9 understand how all of this works and that there are mechanical stresses on
10 these, these -- which is why they break down.

11 JUDGE FREDMAN: -- one of the strongest materials that they
12 happen to be able to read about in the art.

13 MR. ALTMAN: But in fact they -- the art had been -- there was a
14 state of the art, and the state of the art was to use the unreinforced materials,
15 because it wasn't recognized that in these small vascular situations that there
16 really was a problem with --

17 JUDGE GREEN: But you're not limited --

18 MR. ALTMAN: -- with a structural integrity.

19 JUDGE GREEN: -- to small vascular situations.

20 MR. ALTMAN: Well, it says vascular in the claim.

21 JUDGE FREDMAN: It includes --

22 JUDGE GREEN: Are you still --

23 JUDGE FREDMAN: -- blood vessels, and a blood vessel --

24 JUDGE GREEN: Arteries.

25 JUDGE FREDMAN: -- would be as small as a capillary --

1 JUDGE GREEN: I mean, you use the inferior vena cava which is a
2 fairly large --

3 MR. ALTMAN: That's true but it's --

4 JUDGE GREEN: -- in your example which one question I do have
5 about the example is I have no clue what the comparative example is.

6 MR. ALTMAN: It's the same one without the reinforcing --

7 JUDGE GREEN: But the -- what they use, if you can look at page 12
8 of the specification, they use a plain-weave cloth of poly-L-lactic fiber,
9 which is your reinforcing material, right?

10 MR. ALTMAN: That's right, yes.

11 JUDGE GREEN: And then set it in a mold, add a cold polymer, and
12 then they use that as a cellular substrate.

13 MR. ALTMAN: That's right, yes.

14 JUDGE GREEN: So what did they use as a substrate in the
15 comparative example?

16 MR. ALTMAN: Oh, there, there was no reinforcement, so they just
17 poured in the, the biodegradable material.

18 JUDGE GREEN: Where does it say that?

19 MR. ALTMAN: Well, it doesn't but you -- one of -- when you read
20 what's, what's disclosed there, it's clear that that's what they did. It doesn't --
21 I mean it just says -- it says without the reinforcement. So the necessary
22 implication is they did it -- they did the same thing without the
23 reinforcement.

24 JUDGE GREEN: But it appears --

25

1 MR. ALTMAN: Otherwise, there would have been a disclosure of
2 something else --

3 JUDGE FREDMAN: -- for the cells then or they just pour the
4 copolymer in? I'm confused. It's --

5 MR. ALTMAN: No, so the reinforcement was this -- these fibers that
6 they wrapped around the test tube in that experiment.

7 JUDGE GREEN: Right.

8 JUDGE FREDMAN: Right.

9 JUDGE GREEN: But what was their substrate in without because
10 that's, that's what they use for their substrate in the --

11 MR. ALTMAN: That's what they use for, that's what they use for --
12 that's the reinforcement. And then they pour this gel into there.

13 JUDGE FREDMAN: What's the gel composed of?

14 MR. ALTMAN: Well, it says in there. I have to --

15 JUDGE GREEN: The C --

16 MR. ALTMAN: -- have to get this -- get the -- it's a solution of L-
17 lactide-caprolactone-copolymer in dioxane.

18 JUDGE FREDMAN: Okay, so that by itself isn't what was poured in?

19 MR. ALTMAN: That's right. And, and so Judge Fredman, you had
20 raised the issue of, of restenosis and that was really -- that was an earlier
21 iteration of this problem solving, because the initial problem was in using, in
22 using nonresorbable materials that the material that was left behind would
23 lead to stenosis. And so the, the next step was to go to --

24 JUDGE FREDMAN: Not necessarily though. They --

25 MR. ALTMAN: -- biodegradable materials.

1 JUDGE FREDMAN: -- they often use natural -- I mean you do -- you
2 have angioplasty and actually that will be all natural. I mean you're talking
3 about when they did the substitution. You can have restenosis even just with
4 a natural vein.

5 MR. ALTMAN: Well, that can happen to as well but this -- it was
6 originally done as an improvement on the original.

7 JUDGE FREDMAN: Yeah.

8 JUDGE GREEN: Can we move on to Naughton?

9 MR. ALTMAN: Yes, of course.

10 JUDGE GREEN: Because I think we understand your argument as to
11 the first three references.

12 MR. ALTMAN: Yeah, and, and my argument is really quite similar
13 with regard to Naughton, because Naughton, it's interesting, because what he
14 does is he, he puts on the, the reinforcement in Naughton is cellular material,
15 and what he does is he takes, he takes the basic matrix and puts onto, puts
16 onto the matrix -- he seeds it with, with cells such as fibroblasts, and the
17 fibroblasts are there not because they want rigidity. The fibroblasts are there
18 because he wants to, he wants to provide a basis for the subsequent layer of
19 cells. I forgot what he called them, the, the specific cells. He wants to let
20 those specific cells grow in a manner that makes them really comfortable, so
21 he puts a layer of fibroblast on underneath.

22 So although you could broadly characterize those, that first layer of
23 cells, as a bioabsorbable reinforcement, I don't know if I would accept that,
24 but that's what the Examiner did. But it -- I don't want to get into that issue,
25 because in either event, what, what Naughton doesn't address is the whole

1 idea of making a material more structurally rigid by including a
2 bioabsorbable reinforcement in the bioabsorbable matrix to produce
3 something that lowers the risk of catastrophic failure. So, so Naughton, like
4 the other references, doesn't recognize the problem and, and the inventors
5 discovered what the problem was and what the source of that problem was
6 and then implemented a solution to that problem.

7 And so that is what the, that is, that is what the argument for
8 patentability is.

9 JUDGE MILLS: So your argument is that Naughton does not
10 describe a reinforcement?

11 MR. ALTMAN: No, I said I really -- I didn't want to address that
12 issue, because what Naughton doesn't do is that Naughton does not, does not
13 identify either the problem or any, any reason why there would be a risk of
14 sudden failure, and what our invention was the discovery of the source of
15 that cause for sudden failure, was that the materials can break down too fast,
16 because nothing in Naughton even remotely addresses that issue.

17 JUDGE MILLS: Okay, I don't have any further questions. Anything?

18 JUDGE FREDMAN: No.

19 MR. ALTMAN: Okay, I have nothing further to present.

20 JUDGE FREDMAN: Thank you.

21 JUDGE MILLS: Okay, very good.

22 MR. ALTMAN: Thank you.

23 JUDGE MILLS: Thank you very much.

24 (Whereupon, the hearing concluded at 2:16 p.m., on May 21, 2009.)

25